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Registration Decision RD2013-19

Trichoderma asperellum Strain T34

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Registration Decision for *Trichoderma asperellum* Strain T34

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of T34 Biocontrol Technical and T34 Biocontrol, containing the technical grade active ingredient *Trichoderma asperellum* strain T34, to suppress fusarium wilt caused by *Fusarium oxysporum* on greenhouse ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-21, *Trichoderma asperellum strain T34*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Trichoderma asperellum* strain T34 and summarizes the Agency's decision. No comments were received during the consultation process. This decision is consistent with the proposed registration decision stated in PRD2011-21.

For more details on the information presented in this Registration Decision, please refer to PRD2011-21, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Trichoderma asperellum Strain T34?

Trichoderma asperellum strain T34 is a fungus that is used as a microbial pest control agent (MPCA) to control fusarium wilt caused by *Fusarium oxysporum* on greenhouse ornamentals including carnation plants. *Trichoderma asperellum* strain T34 acts by competing directly for space and/or nutrients, by parasitizing the pathogenic fungus, and by inducing plant resistance. The T34 strain of *T. asperellum* was originally isolated from a natural suppressive compost-peat mix in Spain.

Health Considerations

Can Approved Uses of *Trichoderma asperellum* Strain T34 Affect Human Health?

***Trichoderma asperellum* strain T34 is unlikely to affect your health when T34 Biocontrol is used according to the label directions.**

People can be exposed to *T. asperellum* strain T34 when handling and applying T34 Biocontrol. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic byproducts); reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies; and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When *T. asperellum* strain T34 was tested on laboratory animals, there were no signs that it caused disease, nor any toxicity other than minor effects that were quickly resolved. Furthermore *T. asperellum* strain T34 showed no growth at and above 37°C. No adverse effects from *T. asperellum* strain T34 were reported in the published scientific literature.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure that the food Canadians eat is safe.

As there are no direct applications to food, there is no concern for risks posed by dietary exposure of the general population, including infants and children, or animals to *T. asperellum* strain T34.

Occupational Risks From Handling T34 Biocontrol

Occupational risks are not of concern when T34 Biocontrol is used according to label directions, which include protective measures.

Workers using T34 Biocontrol can come into direct contact with *T. asperellum* strain T34 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that workers exposed to T34 Biocontrol must wear waterproof gloves, long-sleeved shirt, long pants, shoes plus socks, eye goggles when handling and a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter).

For bystanders, exposure is expected to be much less than that of workers involved in loading and application activities and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Trichoderma asperellum* Strain T34 Is Introduced Into the Environment?

Environmental risks are not of concern.

Following application, *Trichoderma asperellum* strain T34 is likely able to survive in the environment under favourable environmental conditions (i.e., temperature, humidity) but over time populations of *T. asperellum* strain T34 are expected to return to natural background levels.

The effects of *T. asperellum* strain T34 on soil microorganisms, mushrooms and horticultural crops were examined. These studies showed that *T. asperellum* strain T34 was not toxic or infectious to horticultural crops, and no significant adverse effects were noted on mushrooms and soil microorganisms.

Although avian pulmonary/inhalation/injection, wild mammal, fish, aquatic insect, and earthworms testing were not conducted, adequate information was available to determine that significant adverse effects to these non-target organisms are not expected. There are no published reports of disease associated with *T. asperellum* strain T34 in birds, wild mammals, fish, aquatic insects, and earthworms. Also, minimal exposure to non-target organisms is anticipated from the proposed use of T34 Biocontrol to control *Fusarium oxysporum* in greenhouse ornamentals including carnations.

Value Considerations

What Is the Value of T34 Biocontrol?

T34 Biocontrol is a microbial fungicide that suppresses fusarium wilt caused by Fusarium oxysporum on greenhouse ornamentals.

This product represents an additional disease management tool which could reduce the reliance on conventional fungicides in greenhouse ornamental production.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of T34 Biocontrol to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

As with all microbial pest control products, there are concerns with users developing allergic reactions through repeated high exposures to *T. asperellum* strain T34. Therefore, anyone handling, mixing/loading, or involved in clean-up/repair activities of T34 Biocontrol must wear waterproof gloves, long-sleeved shirt, long pants, shoes plus socks, and a dust/mist filtering respirator/mask (NIOSH approval number prefix TC-21) or NIOSH approved respirators (with any N-95, P-95, R-95 or HE filter).

Environment

As a general precaution, the label prohibits the direct application of the product to aquatic habitats (such as lakes, streams and ponds). The label also directs growers to not allow effluent or run-off from greenhouses containing this product to enter lakes, streams, ponds or other waters and to avoid contaminating surface water by disposal of equipment wash waters.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-21) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.